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MAY 3 0 2013

Section 6 - 510(k) Summary

Date of Summary Preparation: 1/11/2013

1. Submitter's Identifications

Submitter's Name: Guangdong Transtek Medical Electronics Co., Ltd
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2. Correspondent's Identifications

Correspondent's Name: A03 Lab of BTS
Address: No.1 Fanghua Street, Hi-tech Zone, Chengdu City, Sichuan, China
Contact Person: Leo Wang
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3. Name of the Device

Device Classification Name: Analyzer, Body Composition (Impedance Plethysmograph)
Product Name: Body Fat Analyzer
Trade/Proprietary Name: Transtek Body Fat Analyzer
Models: GBF-1251-B, BF-1255-B, BF-1256-B, GBF-1257-B
Classification Panel: Cardiovascular
Common/Usual Name: Body Composition Analyzer/Scales
Product Code: MNW
Device Classification: Class II
Contraindications: Do not use the Analyzer if you have a pacemaker or other internal medical device.

4. The Predicate Devices

Transtek Glass Body Fat Analyzer, Model GBF-950-D, K112932

5. Device Description

Transtek Body Fat Analyzer uses BIA (Bioelectrical Impedance Analysis) technology which passes an electrical current through the body to estimate body fat mass, total body water, muscle mass and bone mass. The electrical current is low and may not be felt. The current passes freely through the fluids contained in muscle tissue, but encounters difficulty/resistance when it passes through fat tissue. This

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resistance of the fat tissue to the current is termed 'Bioelectrical Impedance', and is accurately measured by Transtek Body Fat Analyzer (GBF-1251-B, BF-1255-B, BF-1256-B, and GBF-1257-B).

This method simultaneously calculates personal body fat, total body water, muscle mass, and bone mass, giving a more accurate reading of overall health and fitness. As well as being an analyzer, this device can be used as a conventional weight scale.

The Transtek Body Fat Analyzer embeds a Bluetooth (BT) module that allows it to connect to nearby BT receiving end. The LCD of device displays results. And once measurement is over, the device will start transmission data by BT. Thus users can receive, and display/storage, measurement data of Transtek Body Fat Analyzer unit through their end devices that embedded BT module.

6. Intended Use of Device

The Transtek Body Fat Analyzer measure weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat, total body water percentage, muscle mass, and bone mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.

7. Design Control Activities and Performance Tests Summary

Design control activities for this modification have been implemented and performance tests of modified devices have been done. These performance tests, risk management, and design verification tests provide demonstration that the differences do not raise any new questions of safety and effectiveness.

Proposed Body Fat Analyzer conforms to (including, but not limited to) the following standards:
IEC60601-1-2, Electromagnetic compatibility
IEC60601-1, Electrical safety
ISO14971, Risk management to medical devices
FCC Part 15, EMI tests of FCC Radiation & RF rules and regulations

8. Summary of Substantial Equivalence

8.1 Differences between proposed device and the predicate device

The only significant function difference between the two devices is that the modified device add-on a wireless data communication, what user option, which can transmit measurement results to receiving end equipment.

More modification details are described in this submission.

8.2 Discussion

The Transtek Body Fat Analyzer has identical indication for use, fundamental scientific technology, energy type, and similar performance specifications, dimensional specifications, software/firmware, functions, labeling to the predicate device.

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The only function difference between proposed device and the predicate device is that the modified device provides user an optional wireless data transmission. It is an add-on function that is entirely independent to the body compositions analyzer function. Regardless of wireless connection status, the analyzer normal works to carry out a bioelectrical impedance analysis and display its results.

Thus the wireless data transmission function does not affect the safety and effectiveness of the body analyzer function.

9. Conclusions

The Transtek Body Fat Analyzer (GBF-1251-B, BF-1255-B, BF-1256-B, and GBF-1257-B) is substantially equivalent to the predicate device, GBF-950-D, by having the identical indications for use, identical fundamental scientific technologies, and an add-on function which does not impact the safety and effectiveness of the device.

--- End of this section ---

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 30, 2013

Guandong Transtek Medical Electronics Co., Ltd.
% Mr. Leo Wang
Senior Consultant
A03 Lab of BTS
No. 1 Fanghua Street, Hi-tech District, Chengdu Sichuan
CHINA 610041

Re: K130311
Trade/Device Name: Transtek Body Fat Analyzer
Models: GBF-1251-B, BF-1255-B, BF-1256-B, GBF-1257-B
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: March 7, 2013
Received: March 7, 2013

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Section 5 - Indications for Use

510(k) Number (if known): K130311

Device Name:

Transtek Body Fat Analyzer
Models: GBF-1251-B, BF-1255-B, BF-1256-B, GBF-1257-B

Indications for Use:

The Transtek Body Fat Analyzer measure weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat, total body water percentage, bone mass, and muscle mass in generally healthy adults 18 years of age or older.

It is intended for use in the home/domestic setting only.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130311